FORM PTO-1390
REV. 5-93

US DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEYS DOCKET NUMBER
P01,0443

U.S.APPLICATION NO. (if known, see 37 CFR 1.5)
09/980179

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/SE00.010703	MAY 25, 2000	MAY 28, 1999

TITLE OF INVENTION: **"IMPLANTABLE HEART STIMULATOR WHICH IDENTIFIES THE ORIGIN OF HEART SIGNALS" (AS AMENDED)**

APPLICANT(S) FOR DO/EO/US: **CARL-JOHAN HÖIJER and MARTIN OBEL**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ■ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. □ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ■ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay.
4. ■ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ■ A copy of International Application as filed (35 U.S.C. 371(c)(2))
   a. ■ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. □ has been transmitted by the International Bureau.
   c. □ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ■ A translation of the International Application into English (35 U.S.C. 371(c)(2).
7. ■ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))
   a. □ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. □ have been transmitted by the International Bureau.
   c. ■ have not been made; however, the time limit for making such amendments has NOT expired.
   d. □ have not been made and will not be made.
8. □ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ■ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). **(UNSIGNED)**
10. □ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. □ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; **(PTO 1449, Prior Art, Search Report)**.
12. □ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ■ A FIRST preliminary amendment.
    □ A SECOND or SUBSEQUENT preliminary amendment.
14. □ A substitute specification.
15. □ A change of power of attorney and/or address letter.
16. ■ Other items or information:
    a. ■ Submission of Informal Drawings and Request For Approval of Drawing Changes
    b. ■ **EXPRESS MAIL #EJ552525135US**

U.S.APPLICATION NO. (if known, see 37 C.F.R. 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/980179	PCT/SE00/010703	P01,0443

17. ■ The following fees are submitted:

	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5): Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2) paid to USPTO and International Search Report not prepared by EPO or JPO $1040.00		
No international preliminary examination fee USPTO (37 C.F.R. 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $890.00		
International preliminary examination fee USPTO (37 C.F.R. 1.482) not paid to USPTO but international search fee paid to USPTO (37 C.F.R. 1.445(a)(2) $740.00		
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but all claimd did not satisfy provisions of PCT Article 33(1)-(4) $710.00		
International preliminary examination fee paid to USPTO (37 C F R. 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $100 00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).	$	

Claims	Number Filed	Number Extra	Rate	
Total Claims	6 - 20 =		X $ 18.00	$
Independent Claims	1 - 3 =		X $ 84.00	$
Multiple Dependent Claims			$280.00 +	$
TOTAL OF ABOVE CALCULATIONS =				$
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note: 37 C.F.R. 1.9, 1.27, 1.28)				$
SUBTOTAL =				$
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$
TOTAL NATIONAL FEE =				$ 890.00
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). $40.00 per property **(see separate envelope)** +				$
TOTAL FEES ENCLOSED =				$ 890.00
			Amount to be refunded	$
			charged	$

a. ■ A check in the amount of $ **890.00** cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **501519**. A duplicate copy of this sheet is enclosed.

d ☐ Fees are to be charged to a credit card. **WARNING**: Information on this form may become public. **Credit card information should not be included on this form**. Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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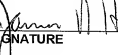

SIGNATURE

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NAME

24,149
Registration Number

BOX PCT

IN THE UNITED STATES DESIGNATED OFFICE

OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER THE PATENT COOPERATION TREATY-CHAPTER II

AMENDMENT "A" PRIOR TO ACTION AND SUBMISSION OF SUBSTITUTE SPECIFICATION

APPLICANTS:	Höijer et al.
ATTORNEY DOCKET NO.	P01,0443
INTERNATIONAL APPLICATION NO:	PCT/SE00/01073
INTERNATIONAL FILING DATE:	May 25, 2000
INVENTION:	"IMPLANTABLE HEART STIMULATOR"

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicants herewith amend the above-referenced PCT application as follows, and request entry of the Amendment prior to examination in the United States National Examination Phase.

IN THE TITLE:

Please cancel the present title and substitute the following title therefor:

--"IMPLANTABLE HEART STIMULATOR WHICH IDENTIFIES THE ORIGIN OF HEART SIGNALS"--

IN THE SPECIFICATION:

Please enter the substitute specification submitted herewith pursuant to 37 C.F.R. §1.125(b). The substitute specification is based on the amended sheets submitted during earlier PCT examination. No new matter is added by substitute specification. A marked-up version of the substitute specification showing all changes is also submitted herewith.

IN THE DRAWINGS:

Please amend each of Figures 1, 2, 3 and 4 as shown on the drawing copies marked in red attached to the Request for Approval of Drawing Changes, filed simultaneously herewith.

IN THE CLAIMS:

On page 11, cancel "Claims" and substitute:

--WE CLAIM AS OUR INVENTION-- therefor.

Please cancel claims 1-6 on amended sheets 11 and 12, and substitute the following claims therefor:

7. An implantable heart stimulator comprising:

a heart signal detector connected to a cardiac lead having an electrode adapted to detect electrical heart signals originating from either a ventricle or an atrium;

at least two detection channels connected to said heart signal detector for receiving said electrical heart signals from said electrode;

each of said detection channels comprising a filter having a filter characteristic, which emits a filtered signal at a filter output, a threshold detector which compares said filtered signal to a threshold and which generates a threshold detector output signal if said filtered signal exceeds said threshold, and a peak amplitude determining unit connected to the output of said filter which generates a peak amplitude value of said filtered signal;

the respective filters in said at least two detection channels having different passbands from each other, and each of said detection channels being continuously active; and

a heart event identifying unit connected to the threshold detector and the peak amplitude determining unit in each of said detection channels which unambiguously identifies, by applying

predetermined heart event identifying criteria to the threshold detector output and the peak amplitude value from each of said detection channels, a type of electrical heart signal detected by said heart signal detector.

8. An implantable heart stimulator as claimed in claim 7 wherein said heart event identifying unit employs heart event identifying criteria selected from the group consisting of a quotient of respective peak amplitude values from two of said detection channels and a difference between respective peak amplitude values from two of said detection channels.

9. An implantable heart stimulator as claimed in claim 7 comprising three of said detection channels, said three detection channels containing respective filters with respective filter characteristics tuned to be sensitive to R-waves, T-waves and PVCs.

10. An implantable heart stimulator as claimed in claim 7 comprising three of said detection channels, and wherein the respective filters in said three detection channels have respective filter characteristics tuned to sensitive to P-waves, a premature atrial contraction and far-field R-waves.

11. An implantable heart stimulator as claimed in claim 7 wherein said heart event identifying unit comprises a tuner control connected to the respective filters in said at least two detection channels for tuning said respective filters.

12. An implantable heart stimulator as claimed in claim 7 wherein said heart event identifying unit employs identifying criteria for identifying types of electrical heart signals selected from the group consisting of R-waves, T-waves, premature ventricular contractions, P-waves, and far-field R-waves.

IN THE ABSTRACT:

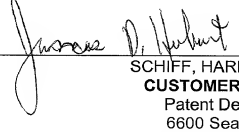
Please add the Abstract set forth in separately numbered page 13, attached hereto.

REMARKS:

The present Amendment makes editorial changes in the title, specification, drawings, claims and adds an Abstract, to bring the present PCT application into conformity with United States patent practice. The claims submitted herein differ in language from original claims 1-6 solely for the purpose of conforming the claims to the requirements of 35 U.S.C. §112, second paragraph. No difference in the claim language between the present claims and the original claims has been made for the purpose of distinguishing any of the claims submitted herein over the teachings of the prior art of record.

Early consideration of the present PCT application on the merits is respectfully requested.

Submitted by,



(Reg. 24,149)

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SUBSTITUTE SPECIFICATION

SPECIFICATION

TITLE

"IMPLANTABLE HEART STIMULATOR WHICH IDENTIFIES THE ORIGIN OF HEART SIGNALS"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to an implantable heart stimulator, e.g. a pacemaker or a defibrillator.

Description of the Prior Art

In conventional pacemaker technology often a single band- pass filter is used in the sensing circuit of the pacemaker in order to detect electrical heart signals. When using this known technique the origin of a signal that caused a sensed event is difficult to determine.

A ventricular event occurring early in the heart cycle (prior to a normally timed QRS-complex) and arising from a focus in the ventricles is often referred to as a premature ventricular contraction (PVC).

If a PVC not is detected due to undersensing it can cause inappropriately timed, asynchronous or competitive stimulation pulses to be delivered. Undersensing is defined as a failure of the pacemaker to sense an electrical signal related to a heart event, e.g. a PVC, due to the sensitivity of the sensing circuit of the pacemaker being set too low. This can often be corrected by programming the pacemaker to a more sensitive setting, i.e. decreasing the value of the sensitivity level.

United States Patent No. 4,880,004 discloses an implantable cardiac stimulator for detecting and treating cardiac arrhythmias. The stimulator includes a sense amplifier responsive to sensed cardiac signals for detecting and distinguishing normal and abnormal cardiac activity within the sensed signals. The sense amplifier includes an automatic gain control amplifier, a filter and a comparator having a pair of signal channels for processing the sensed signals according to different frequency bandpass characteristics to

establish sensing thresholds, margins and signal gain. One of the signal channels constitutes a feedback loop for determining the signal gain and the sensing margin for the other channel.

In United States Patent No. 5,350,402 an atrial defibrillator is disclosed including a first detector for detecting R-waves of the heart and a second detector for detecting T-waves of the heart. The detection criterion is based on a predetermined time interval relationship between the R-wave and the T-wave. According to a software implementation of the T-wave detector, a microprocessor may be implemented for filtering the output of a sense amplifier with a high-pass filter and a low-pass filter. The derivative of the filtered signal is calculated by discrete differentiation of the filtered data and the derivative is re-filtered with a low-pass filter. These values are used in further calculations to determine if a T-wave is detected.

In United States Patent No. 5,755,739 an adaptive and morphological system for discriminating P-Waves and R-waves inside the human body is disclosed. A drawback of a system using morphological recognition is that it probably is not fast enough for real time operation and that it is often implemented by a microprocessor that has unacceptably high energy consumption.

In United States Patent No. 4,305,396 an improved automatically rate adaptive pacemaker is disclosed. The theory behind this patent is that a correlation has been identified between e.g. the amplitudes of the R-wave and T-wave and the heart rate. This correlation is then used to control a rate-responsive pacemaker. The peak values of the QRS-wave and T-wave, respectively, are detected in detection windows using conventional techniques. The detected values are then applied to a correlation block where a rate-controlling signal is generated.

European Application 0 917 887 discloses a cardiac event detecting system for an implantable heart stimulator intended to be connected to the heart of a patient via at least two unipolar electrode leads, or at least one

bipolar electrode lead having one electrode pole in the atrium and one electrode pole in the ventricle, for sensing heart signals. This system has at least two signal channels for signals sensed between the two electrode poles and between one of the electrode poles and the stimulator capsule, respectively.

European Application 0 646 390 discloses a heart stimulator having an atrial electrode in an atrium of a heart and a ventricular electrode in a ventricle in the heart. In order to sense stimulated events in the heart a detector is connected between the atrial and ventricular electrodes to measure electrical heart signals between them.

SUMMARY OF THE INVENTION

An object of the present invention is to improve the safety in detecting electrical heart signals and to make it possible to determine the origin of detected signals. The heart stimulator according to the invention is in particular useful for a safe detection of premature ventricular contractions (PVCs).

Another object of the invention is to arrange an implantable heart stimulator having a detection of electrical heart signals that is fast and low energy consuming.

The above objects are achieved in accordance with the principles of the present invention in an implantable heart stimulator having at least one heart signal detector adapted to detect electrical signals originating from either a ventricle or an atrium, at least two detection channels connected to the detector, each channel including a filter with a predetermined filter characteristic, a threshold detector with a predetermined threshold, and peak amplitude determining unit. In each detection channel, the filter therein generates a filtered signal that is supplied to the threshold detector, which emits a detection signal if the filtered signal exceeds the threshold, and the filtered signal is also supplied to the peak amplitude determining unit which

generates a signal representing the peak amplitude value of the filtered signal.

Each of the detection channels is connected to the same cardiac lead electrode, and each filter has a passband that is different from the passband of the other filters. Each of the channels is continuously active, and the respective signals therefrom are supplied to a heart event identifying unit that unambiguously identifies the type of signal that caused a detected heart event by applying predetermined heart event identifying criteria to the detection channel signals.

DESCRIPTION OF THE DRAWINGS

Figure 1 shows an implantable heart stimulator.

Figure 2 is a block diagram of the implantable heart stimulating device according to the invention.

Figure 3 is a block diagram of a detection channel according to the invention.

Figure 4 is a block diagram of a preferred embodiment of a part of a detection channel according to the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 shows an implantable heart stimulator formed by a heart stimulating device 2 and an electrode lead 4 inserted into the ventricle of a heart 6. The electrode lead 4 is inserted into the heart 6 and arranged in the ventricle according to procedures well known to persons skilled in the art. The heart stimulator in Fig. 1 relates to a single chamber heart stimulator, which means that the electrode lead is arranged in one chamber of the heart, in this case the right ventricle. However, it should be noted that the invention is equally applicable in a dual chamber heart stimulator that has two heart electrode leads adapted to stimulate the heart both in the atrium and in the ventricle, as well as in a multi-chamber heart stimulator adapted to stimulate three or four chambers of the heart.

Figure 2 illustrates the implantable heart stimulating device 2 according to the invention, that has a pulse generator 8 for generating heart stimulating pulses to the heart via the electrode lead 4. The heart stimulating device 2 further has a heart signal detector 10 connected to the electrode lead 4 and adapted to receive electrical heart signals 12 and to generate detected electrical heart signals 14 to three detection channels 16, 16', 16". Each channel is adapted to generate a detection signal 18, 18', 18" and a peak amplitude value 20, 20', 20" to a heart event identifying unit 22 that generates a signal 24 that identifies a detected heart event and applies the signal 24 to a control unit 26.

Figure 3 illustrates one of the detection channels 16. The detection channel 16 has a filter 28 that generates a filtered signal 30 that is applied to a threshold detector 32 and to a peak amplitude determining unit 34. If the filtered signal exceeds a predetermined threshold 36 of the threshold detector 32 the detection signal 18 is generated. The peak amplitude determining unit 34 generates the peak amplitude value 20.

The invention is described in relation to a single chamber heart stimulator, i.e. with one electrode lead placed in the atrium or in the ventricle of the heart. As mentioned above the invention is equally applicable in a dual chamber heart stimulator where, for each electrode lead, a heart signal detection means and at least two detection channels are associated.

Each filter 28 has a predetermined filter characteristic, that differs from that of the filter 28 in another each of the other detection channels.

If the heart signal detector 10 receives signals detected in the ventricle of the heart, the predetermined respective filter characteristics of the filters 28 in three parallel detection channels are e.g. tuned to be sensitive to R-waves, T-waves and PVCs.

The filter 28 sensitive to R-waves is a band-pass filter with a pass-band in the range 20-50 Hz.

The filter 28 sensitive to T-waves is a band-pass filter with a pass-band in the range 2-10 Hz.

And the filter 28 sensitive to PVCs is a band-pass filter with a pass-band typically in the range 15-40 Hz.

If the heart signal detector 10 instead receives signals detected in the atrium of the heart, the predetermined respective filter characteristics of the filters 28 in two parallel detection channels preferably are tuned to be sensitive to P-waves and far-field R-waves. The filter 28 sensitive to P-waves is a band-pass filter with a narrow pass-band around 30 Hz.

The filter 28 sensitive to far-field R-waves is a band- pass filter with a pass-band typically in the range 10-35 Hz.

It is however possible to arrange further detection channels both for detection in the atrium and in the ventricle, e.g. to be able to detect different kinds of arrhythmia, states of atrial or ventricular fibrillation etc.

The filter filters 28 can be implemented using digital or analog filter techniques.

If a digital filter technology is used the analog detected heart signal is A/D converted before filtering is performed, and the processing of the filtered signal in the threshold detector 32 and in the peak amplitude determining unit 34 is digital.

If an analog filter instead is used the above-mentioned processing might also be performed in an analog threshold detector and in an analog peak amplitude determining means. As an alternative the filtered signal is A/D-converted after the filtration and then applied to the threshold detector 32 and the peak amplitude determining unit 34.

The filter characteristics discussed above could either be set at the time of manufacture of the implantable device or could be set by a physician during implantation of the device or later at a follow-up visit. The filters 28 can be automatically tuned by tuning means in the heart event identifying unit 22.

Figure 4 illustrates a preferred embodiment of the threshold detector 32 and the peak amplitude determining unit 34. The filtered signal 30 is a stream of digital bits representing the heart signal. The bit-stream is applied to the threshold detector 32 which is a digital comparator with a threshold 36 that generates the detection signal 18 if the filtered signal exceeds the threshold 36. The detection signal is applied to the peak amplitude determining unit 34 that, according to this embodiment, is a shift register. When a detection signal is received by the determining unit 34, the digital bit-stream is clocked into the shift register during a predetermined time, about 10 - 30 ins. When the predetermined time has elapsed, the content of the shift register is inspected in order to find the maximum value and that value is then generated as the peak amplitude value 20.

According to another preferred embodiment of the invention the heart signal detector 10 receives signals detected in the ventricle of the heart. In figure 2 the detection channel 16 is tuned to be sensitive to R-waves, the detection channel 16' is tuned to be sensitive to T-waves and the detection channel 16" is tuned to be sensitive to PVCs. The detection channel 16 generates detection signal 19 (R_{det}), indicating a detected R-Wave, and a peak amplitude value 20 (R_{max}) indicating the peak amplitude of the detected R-wave. According to the same principles T_{det}, T_{max}, PVC_{det} and PVC_{max} are generated by the detection channels 16', 16", respectively.

The detection signals and the peak amplitude values are received by the heart event identifying unit 22 where a number of heart event identifying criteria are applied.

To unequivocally identify an R-wave the following criteria must be fulfilled:

Detection signal R_{det} received, i.e. no T_{det} or PVC_{det}, and $R_{max}/PVC_{max}>1$ (also $R_{max}/T_{max}>1$ could be checked).

The division R_{max}/PVC_{max} need only be performed if there also was a PVC_{det}.

R_{max}-PVC_{max}>0 can be used instead of R_{max}/PVC_{max}>1.

To unequivocally identify a PVC the following criteria must be fulfilled: Detection signal PVC_{det} received, i.e. no R_{det} or T_{det} and PVC_{max}/R_{max} >1 and PVC_{max}/T_{max} >1 if PVC_{det} and R_{det}.

The division PVC_{max}/R_{max} need only be performed if there also was an R_{det}.

PVC_{max} - R_{max} >* can be used instead of PVC_{max}/R_{max} >1.

Typical values for R_{max} is in the range of 6-12 mV and for PVC_{max} is in the range of 3-6 mV. T_{max} has a maximal peak amplitude below 1 mV.

According to a second preferred embodiment of the invention the heart signal detector 10 receives signals detected in the atrium of the heart. In figure 2 only two detection channels are used and the detection channel 16 is tuned to be sensitive to P-waves and the detection channel 16' is tuned to be sensitive to far field R-waves. The detection channel 16 generates detection signal 18 (P_{det}), indicating a detected P-Wave, and a peak amplitude value 20 (P_{max}) indicating the peak amplitude of the detected P-wave. According to the same principles R (far-field)$_{det}$ and R(farfield)$_{max}$ are generated by the detection channel 16'.

To unequivocally identify a P-wave, the following criteria must be fulfilled:

Detection signal P_{det} received and P_{max}/ R(far-field)$_{max}$>I if P_{det} and R(far-field)$_{det}$.

To unequivocally identify a far-field R-wave the following criteria must be fulfilled:

Detection signal R(far-field)$_{det}$. received and R(far-field) $_{max}/P_{max}$/>I if R(far-field)$_{det}$ and P_{det}.

Typical values for P_{max} when filtered with the P-wave adapted filter 28 is in the range of 3-4 mV and when filtered with the far-field R-wave adapted filter 28 in the range of 2-3 mV. Typical values for R(far-field)$_{max}$ when

filtered with the P-wave adapted filter is in the range of 2-3 mV and when filtered with the far-field R-wave adapted filter 28 in the range of 3-4 mV.

It should be noted that the individual variability regarding signal amplitudes may be significant.

The heart event identifying unit 22 is implemented either by software in a microprocessor or by a digital network using commonly available programming technique or digital network design.

The filters 28 are continuously active which means that each filter 28 in each of the detection channels 16, 16′ and 16″ receives detected electrical heart signals and performs filtering during the whole heart cycle.

As soon as a detection signal is received by the heart event identifying unit 22, the peak amplitude values received during a predetermined time interval, e.g. from * to 30 ms, are used in the above-mentioned identifying criteria to identify the detected heart event.

The signal 24 identifying a detected heart event is applied to the control unit 26 where appropriate action is taken in response of the detected heart event. Such action could be a resetting of certain time intervals, a change of mode of operation for the heart stimulator and/or the adjustment of certain parameters, e.g. the sensitivity level. All these actions are well known to a person skilled in the art of heart stimulators and therefore need not be further described in the present application.

According to still another embodiment of the invention the heart event identifying unit 22 is provided with means for tuning and adjusting each filter 28 to be more sensitive to the heart event it is intended to detect, e.g. R-waves. That could be done by e.g. changing the band-width or another filter parameter of the filter.

In the embodiments of the invention described above the heart signal detection technique is only briefly discussed. It should be noted that any detection technique resulting in a detection of heart signals is applicable in the present invention. The heart signal can be detected by a single bipolar

electrode lead by measuring between a tip and a ring electrode surfaces. If instead a unipolar heart electrode is used detection is performed between a tip electrode surface and an electrode surface at the pacemaker housing. Still another possibility is to detect between electrode surfaces at different electrode leads that could be unipolar, bipolar or multipolar. The above-mentioned measurement techniques and expressions are well known to a person skilled in the art of heart stimulators and are therefore not further described.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

MARKED-UP COPY

[Implantable heart stimulator

Technical field of the invention]

SPECIFICATION

TITLE

"IMPLANTABLE HEART STIMULATOR WHICH IDENTIFIES THE ORIGIN OF HEART SIGNALS"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to an implantable heart stimulator, e.g. a pacemaker or a defibrillator[, according to the preamble of the independent claim].

Description of the Prior Art

[Background of the invention

The purpose of the invention is to improve the detection safety of a heart signal detection means in an implantable heart stimulator.]

In conventional pacemaker technology often a single band- pass filter is used in the sensing circuit of the pacemaker in order to detect electrical heart signals. When using this known technique the origin of a signal that caused a sensed event is difficult to determine.

A ventricular event occurring early in the heart cycle (prior to a normally timed QRS-complex) and arising from a focus in the ventricles is often referred to as a premature ventricular contraction (PVC).

If a PVC not is detected due to undersensing it can [result in that] cause inappropriately timed, asynchronous or competitive stimulation pulses [are] to be delivered. Undersensing is defined as a failure of the pacemaker to sense an electrical signal related to a heart event, e.g. a PVC, due to [that] the sensitivity of the sensing circuit of the pacemaker [is] being set too low. This can often be corrected by programming the pacemaker to a more sensitive setting, i.e. decreasing the value of the sensitivity level.

[US-] United States Patent No. 4,880,004 discloses an implantable cardiac stimulator for detecting and treating cardiac arrhythmias. The stimulator includes a sense amplifier responsive to sensed cardiac signals for detecting and distinguishing normal and abnormal cardiac activity within the sensed signals. The sense amplifier includes an automatic gain control amplifier, a filter and a comparator having a pair of signal channels for processing the sensed signals according to different frequency bandpass characteristics to establish sensing thresholds, margins and signal gain. One of the signal channels constitutes a feedback loop for determining the signal gain and the sensing margin for the other channel.

In [US-] United States Patent No. 5,350,402 an atrial defibrillator is disclosed including a first detector for detecting R-waves of the heart and a second detector for detecting T-waves of the heart. The detection criterion is based on a predetermined time interval relationship between the R-wave and the T-wave. According to a software implementation of the T-wave detector, a microprocessor may be implemented for filtering the output of a sense amplifier with a high-pass filter and a low-pass filter. The derivative of the filtered signal is calculated [using a] by discrete differentiation of the filtered data and the derivative is re-filtered with a low-pass filter. These values are used in further calculations to determine if a T-wave is detected.

In [US-] United States Patent No. 5,755,739 an adaptive and morphological system for discriminating P-Waves and R-waves inside the human body is disclosed. A drawback of a system using morphological recognition is that it probably [not] is not fast enough for real time operation and that it is often implemented by a microprocessor that has [unacceptable] unacceptably high energy consumption.

In [US-] United States Patent No. 4,305,396 an improved automatically rate adaptive pacemaker is disclosed. The theory behind this patent is that a correlation has been identified between e.g. the amplitudes of the R-wave and T-wave and the heart rate. This correlation is then used

to control a rate-responsive pacemaker. The peak values of the QRS-wave and T-wave, respectively, are detected in detection windows using conventional techniques. The detected values are then applied to a correlation block where a rate-controlling signal is generated.

[EP-A-] European Application 0 917 887 discloses a cardiac event detecting system for an implantable heart stimulator intended to be connected to the heart of a patient [through] via at least two unipolar electrode leads, or at least one bipolar electrode lead having one electrode pole in the atrium and one electrode pole in the ventricle, for sensing heart signals[, comprises] This system has at least two signal channels for signals sensed between the two electrode poles and [and] between one of the electrode poles and the stimulator capsule, respectively.

[EP-A-] European Application 0 646 390 discloses a heart stimulator [comprising] having an atrial electrode in an atrium of a heart and a ventricular electrode in a ventricle in the heart. In order to sense stimulated events in the heart a detector is connected between the atrial and ventricular electrodes to measure electrical heart signals between them.

SUMMARY OF THE INVENTION

[One] An object of the present invention is to improve the safety in detecting electrical heart signals and to make it possible to determine the origin of detected signals. The heart stimulator according to the invention is in particular useful for a safe detection of premature ventricular contractions (PVCs).

Another object of the invention is to arrange an implantable heart stimulator having a detection of electrical heart signals that is fast and low energy consuming.

The above objects are achieved in accordance with the principles of the present invention in an implantable heart stimulator having at least one heart signal detector adapted to detect electrical signals originating from either a ventricle or an atrium, at least two detection channels connected to

the detector, each channel including a filter with a predetermined filter characteristic, a threshold detector with a predetermined threshold, and peak amplitude determining unit. In each detection channel, the filter therein generates a filtered signal that is supplied to the threshold detector, which emits a detection signal if the filtered signal exceeds the threshold, and the filtered signal is also supplied to the peak amplitude determining unit which generates a signal representing the peak amplitude value of the filtered signal.

Each of the detection channels is connected to the same cardiac lead electrode, and each filter has a passband that is different from the passband of the other filters. Each of the channels is continuously active, and the respective signals therefrom are supplied to a heart event identifying unit that unambiguously identifies the type of signal that caused a detected heart event by applying predetermined heart event identifying criteria to the detection channel signals.

[Short description of the inventive concept

The above objects are achieved by the invention in accordance with the characterizing portion of the appended main claim. Preferred embodiments are set forth in the dependent claims.

Short description of the appended drawings]

DESCRIPTION OF THE DRAWINGS

Figure 1 shows an implantable heart stimulator.

Figure 2 [shows] is a block diagram of the implantable heart stimulating device according to the invention.

Figure 3 [shows] is a block diagram of a detection channel according to the invention.

Figure 4 [shows] is a block diagram of a preferred embodiment of a part of a detection channel according to the invention.

[Detailed description of preferred embodiments of the invention]

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 [discloses] shows an implantable heart stimulator [comprising] formed by a heart stimulating device 2 and an electrode lead 4 inserted into the ventricle of a heart 6. The electrode lead 4 is inserted into the heart 6 and arranged in the ventricle according to procedures well known to persons skilled in the art. The heart stimulator [disclosed] in Fig. 1 relates to a single chamber heart stimulator, which means that the electrode lead is arranged in one chamber of the heart, in this case the right ventricle. However, it should be noted[,] that the invention is equally applicable in a dual chamber heart stimulator that [comprises] has two heart electrode leads adapted to stimulate the heart both in the atrium and in the ventricle [and also], as well as in a multi-chamber heart stimulator adapted to stimulate three or four chambers of the heart.

Figure 2 [discloses] illustrates the implantable heart stimulating device 2 according to the invention, that [comprises] has a pulse generator 8 for generating heart stimulating pulses to the heart via the electrode lead 4. The heart stimulating device 2 further [comprises] has a heart signal [detecting means] detector 10 connected to the electrode lead 4 and adapted to receive electrical heart signals 12 and to generate detected electrical heart signals 14 to three detection channels 16, 16', 16". Each channel is adapted to generate a detection signal 18, 18', 18" and a peak amplitude value 20, 20', 20" to a heart event identifying [means] unit 22 that generates a signal 24 that identifies a detected heart event and applies [said] the signal 24 to a control [means] unit 26.

Figure 3 [discloses] illustrates one of the detection channels 16. The detection channel 16 [comprises] has a filter [means] 28 that generates a filtered signal 30 that is applied to a threshold detector 32 and to a peak amplitude determining [means] unit 34. If the filtered signal exceeds a predetermined threshold 36 of [said] the threshold detector 32 the detection

signal 18 is generated. The peak amplitude determining [means] unit 34 generates [said] the peak amplitude value 20.

The invention is described in relation to a single chamber heart stimulator, i.e. with one electrode lead placed in the atrium or in the ventricle of the heart. As mentioned above the invention is equally applicable in a dual chamber heart stimulator where, for each electrode lead, a heart signal detection means and at least two detection channels are associated.

Each filter [means] 28 has a predetermined filter [characteristics] characteristic, that differs from that of [a] the filter 28 [means] in another each of the other detection [channel] channels.

If the heart signal [detection means] detector 10 receives signals detected in the ventricle of the heart, the predetermined respective filter characteristics of the [filter means] filters 28 in three parallel detection channels are e.g. tuned to be sensitive to R-waves, T-waves and PVCs[, respectively].

The filter [means] 28 sensitive to R-waves is a band-pass filter with a pass-band in the range 20-50 Hz.

The filter [means] 28 sensitive to T-waves is a band-pass filter with a pass-band in the range 2-10 Hz.

And the filter [means] 28 sensitive to PVCs is a band-pass filter with a pass-band typically in the range 15-40 Hz.

If the heart signal [detection means] detector 10 instead receives signals detected in the atrium of the heart, the predetermined respective filter characteristics of the [filter means] filters 28 in two parallel detection channels preferably are tuned to be sensitive to P-waves and far-field R-waves[, respectively]. The filter [means] 28 sensitive to P-waves is a band-pass filter with a narrow pass-band around 30 Hz.

The filter [means] 28 sensitive to far-field R-waves is a band- pass filter with a pass-band typically in the range 10-35 Hz.

It is however possible to arrange further detection channels both for detection in the atrium and in the ventricle[. E.g.], e.g. to be able to detect different kinds of arrhythmia, states of atrial or ventricular fibrillation etc.

The filter [means] filters 28 can be implemented using digital or analog filter techniques.

If a digital filter technology is used the analog detected heart signal is A/D converted before [filtration] filtering is performed, and the processing of the filtered signal in the threshold detector 32 and in the peak amplitude determining [means] unit 34 is digital.

If an analog filter instead is used the above-mentioned processing might also be performed in an analog threshold detector and in an analog peak amplitude determining means. As an alternative the filtered signal is A/D-converted after the filtration and then applied to the threshold detector 32 and the peak amplitude determining [means] unit 34.

The filter characteristics discussed above could either be set at the time of manufacture of the implantable device or could be set by a physician during implantation of the device or later at a follow-up visit. The [filter means could] filters 28 can be automatically tuned by tuning means in the heart event identifying [means] unit 22.

Figure 4 [discloses] illustrates a preferred embodiment of the threshold detector 32 and the peak amplitude determining [means] unit 34. The filtered signal 30 [comprises] is a stream of digital bits representing the heart signal. The bit-stream is applied to the threshold detector 32 which is a digital comparator with a threshold 36 that generates the detection signal 18 if the filtered signal exceeds [said] the threshold 36. The detection signal is applied to the peak amplitude determining [means] unit 34 that, according to this embodiment, is a shift register. When a detection signal is received by the determining [means] unit 34, the digital bit-stream is clocked into the shift register during a predetermined time, about 10 - 30 ins. When the predetermined time has elapsed, the content of the shift register is inspected

in order to find the maximum value and that value is then generated as the peak amplitude value 20.

According to another preferred embodiment of the invention the heart signal [detection means] detector 10 receives signals detected in the ventricle of the heart. In figure 2 the detection channel 16 is tuned to be sensitive to R-waves, the detection channel 16' is tuned to be sensitive to T-waves and the detection channel 16" is tuned to be sensitive to PVCs. The detection channel 16 generates detection signal 19 (R_{det}), indicating a detected R-Wave, and a peak amplitude value 20 (R_{max}) indicating the peak amplitude of the detected R-wave. According to the same principles T_{det}, T_{max}, PVC_{det} and PVC_{max} are generated by the detection channels 16', 16", respectively.

The detection signals and the peak amplitude values are received by the heart event identifying [means] unit 22 where a number of heart event identifying criteria are applied.

To unequivocally identify an R-wave the following criteria must be fulfilled:

Detection signal R_{det} received, i.e. no T_{det} or PVC_{det}, and $R_{max}/PVC_{max}>1$ (also $R_{max}/T_{max}>1$ could be checked).

The division R_{max}/PVC_{max} need only be performed if there also was a PVC_{det}.

$R_{max}-PVC_{max}>0$ can be used instead of $R_{max}/PVC_{max}>1$.

To unequivocally identify a PVC the following criteria must be fulfilled: Detection signal PVC_{det} received, i.e. no R_{det} or T_{det} and $PVC_{max}/R_{max}>1$ and $PVC_{max}/T_{max}>1$ if PVC_{det} and R_{det}.

The division PVC_{max}/R_{max} need only be performed if there also was an R_{det}.

$PVC_{max} - R_{max} >*$ can be used instead of $PVC_{max}/R_{max}>1$.

Typical values for R_{max} is in the range of 6-12 mV and for PVC_{max} is in the range of 3-6 mV. T_{max} has a maximal peak amplitude below 1 mV.

According to a second preferred embodiment of the invention the heart signal [detection means] detector 10 receives signals detected in the atrium of the heart. In figure 2 only two detection channels are used and the detection channel 16 is tuned to be sensitive to P-waves and the detection channel 16' is tuned to be sensitive to far field R-waves. The detection channel 16 generates detection signal 18 (P_{det}), indicating a detected P-Wave, and a peak amplitude value 20 (P_{max}) indicating the peak amplitude of the detected P-wave. According to the same principles R (far-field)$_{det}$ and R(farfield)$_{max}$ are generated by the detection channel 16'.

To unequivocally identify a P-wave, the following criteria must be fulfilled:

Detection signal P_{det} received and P_{max}/ R(far-field)$_{max}$>I if P_{det} and R(far-field)$_{det}$.

To unequivocally identify a far-field R-wave the following criteria must be fulfilled:

Detection signal R(far-field)$_{det}$. received and R(far-field) $_{max}$/P_{max}/>I if R(far-field)$_{det}$ and P_{det}.

Typical values for P_{max} when filtered with the P-wave adapted filter 28 is in the range of 3-4 mV and when filtered with the far-field R-wave adapted filter 28 in the range of 2-3 mV. Typical values for R(far-field)$_{max}$ when filtered with the P-wave adapted filter is in the range of 2-3 mV and when filtered with the far-field R-wave adapted filter 28 in the range of 3-4 mV.

It should be noted that the individual variability regarding signal amplitudes may be significant.

The heart event identifying [means] unit 22 is implemented either by software in a microprocessor or by a digital network using commonly available programming technique or digital network design[, respectively].

The [filter means] filters 28 are continuously active which means that each filter [means] 28 in each of the detection channels 16, 16′ and 16″ receives detected electrical heart signals and performs [filtration] filtering during the whole heart cycle.

As soon as a detection signal is received by the heart event identifying [means] unit 22, the peak amplitude values received during a predetermined time interval, e.g. from * to 30 ms, are used in the above-mentioned identifying criteria to identify the detected heart event.

The signal 24 identifying a detected heart event is applied to the control [means] unit 26 where appropriate action is taken in response of the detected heart event. [That] Such action could be [the reset] a resetting of certain time intervals, [the] a change of mode of operation for the heart stimulator [and] and/or the adjustment of certain parameters, e.g. the sensitivity level. All [this] these actions are well known to a person skilled in the art of heart stimulators and therefore need not be further described in the present application.

According to still another embodiment of the invention the heart event identifying [means] unit 22 is provided with means for tuning and adjusting [the] each filter [means] 28 to be more sensitive to the heart event it is intended to detect, e.g. R-waves. That could be done by e.g. changing the band-width or another filter parameter of the filter.

In the embodiments of the invention described above the heart signal detection technique is only briefly discussed. It should be noted that any detection technique resulting in a detection of heart signals is applicable in the present invention. The heart signal can be detected by a single bipolar electrode lead by measuring between a tip and a ring electrode surfaces. If instead a unipolar heart electrode is used detection is performed between a tip electrode surface and an electrode surface at the pacemaker housing. Still another possibility is to detect between electrode surfaces at different electrode leads that could be unipolar, bipolar or multipolar. The above-

mentioned measurement techniques and expressions are well known to a person skilled in the art of heart stimulators and are therefore not further described.

[The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above embodiments should not be taken as limiting the scope of the invention, which is defined by the appending claims.]

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

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Implantable heart stimulator

Technical field of the invention

The present invention relates to an implantable heart stimulator, e.g. a pacemaker or a defibrillator, according to the preamble of the independent claim.

Background of the invention

The purpose of the invention is to improve the detection safety of a heart signal detection means in an implantable heart stimulator.

In conventional pacemaker technology often a single band-pass filter is used in the sensing circuit of the pacemaker in order to detect electrical heart signals. When using this known technique the origin of a signal that caused a sensed event is difficult to determine.

A ventricular event occurring early in the heart cycle (prior a normally timed QRS-complex) and arising from a focus in the ventricles is often referred to as a premature ventricular contraction (PVC).

If a PVC not is detected due to undersensing it can result in that inappropriately timed, asynchronous or competitive stimulation pulses are delivered. Undersensing is defined as a failure of the pacemaker to sense an electrical signal related to a heart event, e.g. a PVC, due to that the sensitivity of the sensing circuit of the pacemaker is too low. This can often be corrected by programming the pacemaker to a more sensitive setting, i.e. decreasing the value of the sensitivity level.

US-4,880,004 discloses an implantable cardiac stimulator for detecting and treating cardiac arrhythmias. The stimulator includes a sense amplifier responsive to sensed cardiac signals for detecting and distinguishing normal and abnormal

cardiac activity within the sensed signals. The sense amplifier includes an automatic gain control amplifier, a filter and a comparator having a pair of signal channels for processing the sensed signals according to different frequency bandpass characteristics to establish sensing thresholds, margins and signal gain. One of the signal channels constitutes a feedback loop for determining the signal gain and the sensing margin for the other channel.

In US-5,350,402 an atrial defibrillator is disclosed including a first detector for detecting R-waves of the heart and a second detector for detecting T-waves of the heart. The detection criterion is based on a predetermined time interval relationship between the R-wave and the T-wave. According to a software implementation of the T-wave detector a microprocessor may be implemented for filtering the output of a sense amplifier with a high-pass filter and a low-pass filter. The derivative of the filtered signal is calculated using a discrete differentiation of the filtered data and re-filtered with a low-pass filter. These values are used in further calculations to determine if a T-wave is detected.

In US-5,755,739 an adaptive and morphological system for discriminating P-Waves and R-waves inside the human body is disclosed. A drawback of a system using morphological recognition is that it probably not is fast enough for real time operation and that it is often implemented by a microprocessor that has unacceptable high energy consumption.

In US-4,305,396 an improved automatically rate adaptive pacemaker is disclosed. The theory behind this patent is that a correlation has been identified between e.g. the amplitudes of the R-wave and T-wave and the heart rate. This correlation is then used to control a rate-responsive pacemaker. The peak values of the QRS-wave and T-wave,

respectively, are detected in detection windows using conventional techniques. The detected values are then applied to a correlation block where a rate-controlling signal is generated.

EP-A-0 917 887 discloses a cardiac event detecting system for an implantable heart stimulator intended to be connected to the heart of a patient through at least two unipolar electrode leads or at least one bipolar electrode lead having one electrode pole in the atrium and one electrode pole in the ventricle for sensing heart signals, comprises at least two signal channels for signals sensed between the two electrode poles and and between one of the electrode poles and the stimulator capsule respectively.

EP-A-0 646 390 discloses a heart stimulator comprising an atrial electrode in an atrium of a heart and a ventricular electrode in a ventricle in the heart. In order to sense stimulated events in the heart a detector is connected between the atrial and ventricular electrodes to measure electrical heart signals between them.

One object of the present invention is to improve the safety in detecting electrical heart signals and to make it possible to determine the origin of detected signals. The heart stimulator according to the invention is in particular useful for a safe detection of premature ventricular contractions (PVCs).

Another object of the invention is to arrange an implantable heart stimulator having a detection of electrical heart signals that is fast and low energy consuming.

Short description of the inventive concept

The above objects are achieved by the invention in accordance with the characterizing portion of the appended

main claim. Preferred embodiments are set forth in the dependent claims.

Short description of the appended drawings

Figure 1 shows an implantable heart stimulator.
Figure 2 shows a block diagram of the implantable heart stimulating device according to the invention.
Figure 3 shows a block diagram of a detection channel according to the invention.
Figure 4 shows a block diagram of a preferred embodiment of a part of a detection channel according to the invention.

Detailed description of preferred embodiments of the invention

Figure 1 discloses an implantable heart stimulator comprising a heart stimulating device 2 and an electrode lead 4 inserted into the ventricle of a heart 6. The electrode lead is inserted into the heart and arranged in the ventricle according to procedures well known to persons skilled in the art. The heart stimulator disclosed in Fig. 1 relates to a single chamber heart stimulator, which means that the electrode lead is arranged in one chamber of the heart, in this case the right ventricle. However, it should be noted, that the invention is equally applicable in a dual chamber heart stimulator that comprises two heart electrode leads adapted to stimulate the heart both in the atrium and in the ventricle and also in a multi-chamber heart stimulator adapted to stimulate three or four chambers of the heart.

Figure 2 discloses the implantable heart stimulating device 2 according to the invention that comprises a pulse generator 8 for generating heart stimulating pulses to the heart via electrode lead 4. The heart stimulating device 2 further comprises a heart signal detecting means 10

connected to the electrode lead 4 and adapted to receive electrical heart signals 12 and to generate detected electrical heart signals 14 to three detection channels 16, 16', 16''. Each channel is adapted to generate a detection signal 18, 18', 18'' and a peak amplitude value 20, 20', 20'' to a heart event identifying means 22 that generates a signal 24 that identifies a detected heart event and applies said signal to a control means 26.

Figure 3 discloses one of the detection channels 16. The detection channel 16 comprises a filter means 28 that generates a filtered signal 30 that is applied to a threshold detector 32 and to a peak amplitude determining means 34. If the filtered signal exceeds a predetermined threshold 36 of said threshold detector 32 the detection signal 18 is generated. The peak amplitude determining means 34 generates said peak amplitude value 20.

The invention is described in relation to a single chamber heart stimulator, i.e. with one electrode lead placed in the atrium or in the ventricle of the heart. As mentioned above the invention is equally applicable in a dual chamber heart stimulator where, for each electrode lead, a heart signal detection means and at least two detection channels are associated.

Each filter means 28 has a predetermined filter characteristics, that differs from that of a filter means in another detection channel.

If the heart signal detection means 10 receives signals detected in the ventricle of the heart, the predetermined filter characteristics of the filter means in three parallel detection channels are e.g. tuned to be sensitive to R-waves, T-waves and PVCs, respectively.

The filter means sensitive to R-waves is a band-pass filter with a pass-band in the range 20-50 Hz.

The filter means sensitive to T-waves is a band-pass filter with a pass-band in the range 2-10 Hz.
And the filter means sensitive to PVCs is a band-pass filter with a pass-band typically in the range 15-40 Hz.

If the heart signal detection means 10 instead receives signals detected in the atrium of the heart, the predetermined filter characteristics of the filter means in two parallel detection channels preferably are tuned to be sensitive to P-waves and far-field R-waves, respectively.
The filter means sensitive to P-waves is a band-pass filter with a narrow pass-band around 30 Hz.
The filter means sensitive to far-field R-waves is a band-pass filter with a pass-band typically in the range 10-35 Hz.
It is however possible to arrange further detection channels both for detection in the atrium and in the ventricle. E.g. to be able to detect different kinds of arrhythmia, states of atrial or ventricular fibrillation etc.

The filter means can be implemented using digital or analog filter techniques.
If a digital filter is used the analog detected heart signal is A/D converted before filtration is performed and the processing of the filtered signal in the threshold detector and in the peak amplitude determining means is digital.

If an analog filter instead is used the above-mentioned processing might also be performed in an analog threshold detector and in an analog peak amplitude determining means. As an alternative the filtered signal is A/D-converted after the filtration and then applied to the threshold detector and the peak amplitude determining means.

The filter characteristics discussed above could either be set at the manufacture of the implantable device or could be set by a physician during implantation of the device or

later at a follow-up visit. The filter means could be automatically tuned by tuning means in the heart event identifying means.

Figure 4 discloses a preferred embodiment of the threshold detector 32 and the peak amplitude determining means 34. The filtered signal 30 comprises a stream of digital bits representing the heart signal. The bit-stream is applied to the threshold detector 32 which is a digital comparator with a threshold 36 that generates the detection signal 18 if the filtered signal exceeds said threshold. The detection signal is applied to the peak amplitude determining means 34 that, according to this embodiment, is a shift register. When a detection signal is received by the determining means 34, the digital bit-stream is clocked into the shift register during a predetermined time, about 10 - 30 ms. When the predetermined time has elapsed, the content of the shift register is inspected in order to find the maximum value and that value is then generated as the peak amplitude value 20.

According to another preferred embodiment of the invention the heart signal detection means receives signals detected in the ventricle of the heart. In figure 2 the detection channel 16 is tuned to be sensitive to R-waves, the detection channel 16' is tuned to be sensitive to T-waves and the detection channel 16'' is tuned to be sensitive to PVCs. The detection channel 16 generates detection signal 18 (R_{det}), indicating a detected R-Wave, and a peak amplitude value 20 (R_{max}) indicating the peak amplitude of the detected R-wave. According to the same principles T_{det}, T_{max}, PVC_{det} and PVC_{max} are generated by the detection channels 16', 16'', respectively.

The detection signals and the peak amplitude values are received by the heart event identifying means 22 where a number of heart event identifying criteria are applied.

To unequivocally identify an R-wave the following criteria must be fulfilled:
Detection signal R_{det} received, i.e. no T_{det} or PVC_{det}, and $R_{max}/PVC_{max}>1$ (also $R_{max}/T_{max}>1$ could be checked).
The division R_{max}/PVC_{max} need only be performed if there also was a PVC_{det}.
$R_{max}-PVC_{max}>0$ can be used instead of $R_{max}/PVC_{max}>1$.

To unequivocally identify a PVC the following criteria must be fulfilled:
Detection signal PVC_{det} received, i.e. no R_{det} or T_{det} and $PVC_{max}/R_{max}>1$ and $PVC_{max}/T_{max}>1$ if PVC_{det} and R_{det}.
The division PVC_{max}/R_{max} need only be performed if there also was an R_{det}.
$PVC_{max} - R_{max}>0$ can be used instead of $PVC_{max}/R_{max}>1$.
Typical values for R_{max} is in the range of 6-12 mV and for PVC_{max} is in the range of 3-6 mV. T_{max} has a maximal peak amplitude below 1 mV.

According to a second preferred embodiment of the invention the heart signal detection means receives signals detected in the atrium of the heart. In figure 2 only two detection channels are used and the detection channel 16 is tuned to be sensitive to P-waves and the detection channel 16' is tuned to be sensitive to far field R-waves. The detection channel 16 generates detection signal 18 (P_{det}), indicating a detected P-Wave, and a peak amplitude value 20 (P_{max}) indicating the peak amplitude of the detected P-wave. According to the same principles $R(far\text{-}field)_{det}$ and $R(far\text{-}field)_{max}$ are generated by the detection channel 16'.

To unequivocally identify a P-wave the following criteria must be fulfilled:
Detection signal P_{det} received and $P_{max}/R(far\text{-}field)_{max}>1$ if P_{det} and $R(far\text{-}field)_{det}$.

To unequivocally identify a far-field R-wave the following criteria must be fulfilled:
Detection signal $R(far\text{-}field)_{det}$. received and $R(far\text{-}field)_{max}/P_{max}/>1$ if $R(far\text{-}field)_{det}$ and P_{det}.

Typical values for P_{max} when filtered with the P-wave adapted filter is in the range of 3-4 mV and when filtered with the far-field R-wave adapted filter in the range of 2-3 mV. Typical values for $R(far\text{-}field)_{max}$ when filtered with the P-wave adapted filter is in the range of 2-3 mV and when filtered with the far-field R-wave adapted filter in the range of 3-4 mV.
It should be noted that the individual variability regarding signal amplitudes may be significant.

The heart event identifying means 22 is implemented either by software in a microprocessor or by a digital network using commonly available programming technique or digital network design, respectively.

The filter means are continuously active which means that each filter means in each of the detection channels receives detected electrical heart signals and performs filtration during the whole heart cycle.
As soon as a detection signal is received by the heart event identifying means the peak amplitude values received during a predetermined time interval, e.g. from 0 to 30 ms, are used in the above-mentioned identifying criteria to identify the detected heart event.

The signal 24 identifying a detected heart event is applied to the control means 26 where appropriate action is taken in response of the detected heart event. That could be the reset of certain time intervals, the change of mode of operation for the heart stimulator and the adjustment of certain parameters, e.g. the sensitivity level. All this actions are well known to a person skilled in the art of

heart stimulators and therefore not further described in the present application.

According to still another embodiment of the invention the heart event identifying means 22 is provided with means for tuning and adjusting the filter means to be more sensitive to the heart event it is intended to detect, e.g. R-waves. That could be done by e.g. changing the band-width or another filter parameter of the filter.

In the embodiments of the invention described above the heart signal detection technique is only briefly discussed. It should be noted that any detection technique resulting in a detection of heart signals is applicable in the present invention. The heart signal can be detected by a single bipolar electrode lead by measuring between a tip and a ring electrode surfaces. If instead a unipolar heart electrode is used detection is performed between a tip electrode surface and an electrode surface at the pacemaker housing. Still another possibility is to detect between electrode surfaces at different electrode leads that could be unipolar, bipolar or multipolar. The above-mentioned measurement techniques and expressions are well known to a person skilled in the art of heart stimulators and are therefore not further described.

The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above embodiments should not be taken as limiting the scope of the invention, which is defined by the appending claims.

Claims

1. Implantable heart stimulator comprising at least one heart signal detection means adapted to detect electrical heart signals originating from either a ventricle or from an atrium and to apply said signals to at least two detection channels (16,16',16''), each channel comprises a filter means (28) with a predetermined filter characteristic, a threshold detector (32) with a predetermined threshold (36) and a peak amplitude determining means (34), wherein said filter means generates a filtered signal (30) that is applied to said threshold detector that generates a detection signal (18,18',18'') if said filtered signal exceeds said threshold and to said peak amplitude determining means that generates a peak amplitude value (20,20',20'') of said filtered signal **characterized in** that each of the said channels are connected to the same electrode, each of said channels have a filter with a passband that is different from the passband of the filter in other channels, each of said channels are continously active, said heart stimulator further comprises a heart event identifying means (22) that unequivocally identifies, by applying predetermined heart event identifying criteria, the type of signal that caused a detected heart event.

2. Implantable heart stimulator according to claim 1 **characterized in** that said identifying criteria include forming the quote and/or the difference between peak amplitude values provided that at least one detection signal is received by the heart event identifying means.

3. Implantable heart stimulator according to any preceding claim **characterized in** that said predetermined filter characteristics for filter means in different detection channels are tuned to be sensitive to R-waves, T-waves and PVCs, respectively.

4. Implantable heart stimulator according to any preceding claim **characterized in** that said predetermined filter characteristics for filter means in different detection channels are tuned to be sensitive to P-waves, PAC (premature atrial contraction) and far-field R-waves, respectively.

5. Implantable heart stimulator according to any preceding claim **characterized in** that said heart event identifying means comprises tuning means adapted to tune said filter means.

6. Implantable heart stimulator according to any preceding claim **characterized in** that said detected heart event could be any of the following: an R-wave, a T-wave, a PVC, a P-wave or a far-field R-wave.

ABSTRACT OF THE DISCLOSURE

An implantable heart stimulator has a heart signal detector adapted to detect electrical heart signals and to apply the detected signals to at least two detection channels. Each detection channel includes a filter, with each filter having a passband that differs from the passband of the other filters. Each channel also includes a threshold detector and a peak amplitude determining unit connected to the output of the filter in that channel. A heart event identifying unit is connected to the outputs of each channel and unambiguously identifies a type of signal which produced a detected heart event by applying predetermined identifying criteria to the outputs of the threshold detector and the peak amplitude determining unit from each channel.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	ATTORNEY'S DOCKET NUMBER P01,0443

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"IMPLANTABLE HEART STIMULATOR WHICH IDENTIFIES THE ORIGIN OF HEART SIGNALS" (AS AMENDED)

the specification of which (check only one item below):

- ☐ is attached hereto.
- ■ was filed as United States application
  Serial No. 09/980,179
  on November 28, 2001,
  and was amended
  on November 28, 2001 (if applicable).
- ☐ was filed as PCT international application
  Number _____
  on _____,
  and was amended under PCT Article 19
  on _____ (if applicable).

I hereby state that I have reviewed and understand the contest of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (If PCT indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
SWEDEN	9901966-3	28.05.99	■ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

Combined Declaration For Patent Application and Power of Attorney (Continued)
(Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NO. P01,0443

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject mater of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.

PCT APPLICATION NO	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected herewith.

And I hereby appoint all Attorneys identified by the United States Patent & Trademark Office Customer Number 26574, who are all members of the firm of Schiff, Hardin & Waite.

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Patent Department
6600 Floor Sears Tower, Chicago, Illinois 60606
Customer Number 26574

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2001	FULL NAME OF INVENTOR	FAMILY NAME **HOIJER**	FIRST GIVEN NAME **JOHAN-CARL**	SECOND GIVEN NAME
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	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE April 1, 2002	DATE APRIL 3 2002	DATE

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